JUL 15 2003

K031273

XI. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS. May 30, 1997.
[Separate Page]

I. Submitter: Greg Wiita, Amertek Medical, Inc., 2655 North Ocean Drive, Singer Island, Florida 33404.

II. Classification Names and numbers: Accessory to Ultrasound Probe, Stepping Device, Code ITX. Accessory to Remote Controlled Radionuclide Applicator System, Code JAQ

III. Common/Usual Name: Template for Seeding Device; Probe Stabilization Device, Applicator for Remote Controlled Afterloading Brachytherapy.

IV. Proprietary Names: Sure-Point™ HDR Needle Template

V. Establishment Registration Number: 1066424

VI. Classification: Acc. to ultrasonic transducer, Class II, CFR 892.1570;
Acc. to Remote controlled radionuclide applicator system, Class II, CFR 892.5700.

VII. Substantial Equivalence: Sure-Point™ HDR Needle Template is substantially equivalent to its predicate device, Sure-Point Brachytherapy Template cleared under K011581 and to HDR templates cleared by Nucletron in K003270, Mick Radio-Nuclear in K993400, and related devices.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, as the equivalent devices cleared for marketing by the 510(k) process under K003270 and K990990 by Nucletron, K993400 by Mick Radio-Nuclear Instruments, and K910862 by Best industries.

2. The technological characteristics for this product are the same as those for the predicate devices and those currently on the market. Minor differences in structure would not be expected to provide different results.

3. Descriptive information provided shows that the materials from which Amertek™ is made are substantially equivalent to those of similar products, used for identical purposes, currently on the market.

4. The FDA "Decision-Making Process" chart was used and appears in Attachment V.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2003

Mr. Greg Wiita
President
Amertek Medical Inc.
2655 North Ocean Drive
SINGER ISLAND FL 33404

Re: K031273
Trade/Device Name: Amertek™ Brachytherapy Template
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: 90 JAQ
Dated: April 16, 2003
Received: April 23, 2003

Dear Mr. Wiita:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

VIII. Indications for Use: [Separate Page]

510(k) Number: NA K031273

Device Name: Amertek™ Brachytherapy Template

The use of sealed radioisotopes to treat tumors within the body has been documented and published since the turn of the century. Modern era radiation therapy has developed delivery systems using isotopes of cesium, iridium, iodine and gold, for a few examples. Many tumors now are treated by internal exposure to radiation emitted from sealed radioactive sources. The two common modalities are the Low dose rate and High dose rate afterloaders.

The Sure-Point™ HDR Needle Template is designed to allow precision ultrasound probe alignment, placement and position retention of HDR needles in cancer treatments. It was designed to work with commercially available high dose rate remote afterloaders. A specific application is the treatment of prostate (or other) cancer.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

David R. Lyman (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031273